



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,940	08/31/2001	Han-Mo Koo	38345-174995	8963

26694 7590 12/18/2002

VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,940

Applicant(s)

KOO ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Election/Restrictions***

It is noted that the claims of the instant application have been determined to include linking claims 1 and 8. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 8. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. This application contains claims directed to the following patentably distinct inventions linked by claims 1 and 8:

Group I. Claims 1-3, 6-7, 9-12, 15-18, 21, drawn to a method of killing melanoma cells or inducing an antitumor response in a mammal having melanoma, using an inhibitor of the MAPK pathway, which is *Bacillus anthracis* lethal factor, a MEK1 and MEK2-directed protease, classified in class 424, subclass 9.2.

Art Unit: 1642

Group II. Claims 1-2, 6-7, 9-11, 15-17, 21, drawn to a method of killing melanoma cells or inducing an antitumor response in a mammal having melanoma, using an inhibitor of the MAPK pathway, which is a *Yersinia* protein, a MEK1-directed protease, as disclosed in the specification on page 12, paragraph before last, classified in class 424, subclass 9.2.

Group III. Claims 1, 4-7, 9-10, 13-16, 19-21, drawn to a method of killing melanoma cells or inducing an antitumor response in a mammal having melanoma, using an inhibitor of the MAPK pathway, which is PD98059, a small organic molecule, classified in class 424, subclass 9.2.

Group IV. Claims 1, 4-7, 9-10, 13-16, 19-21, drawn to a method of killing melanoma cells or inducing an antitumor response in a mammal having melanoma, using an inhibitor of the MAPK pathway, which is U0126, a small organic molecule, classified in class 424 subclass 9.2.

Group V. Claims 1, 4-7, 9-10, 13-16, 19-21, drawn to a method of killing melanoma cells or inducing an antitumor response in a mammal having melanoma, using an inhibitor of the MAPK pathway, which is PD184352, a small organic molecule, classified in class 424, subclass 9.2.

Group VI. Claims 8, 16-18, 21, drawn to a method for protecting against melanoma in a susceptible subject, who is at risk for development of melanoma, or at risk for recurrence of melanoma, comprising administering an inhibitor of the MAPK pathway, which is *Bacillus anthracis* lethal factor, a MEK1 and MEK2-directed protease, classified in class 424, subclass 9.2.

Art Unit: 1642

Group VII. Claims 8, 16-18, 21, drawn to a method for protecting against melanoma in a susceptible subject, who is at risk for development of melanoma, or at risk for recurrence of melanoma, comprising administering an inhibitor of the MAPK pathway, which is a *Yersinia* protein, a MEK1-directed protease, as disclosed in the specification on page 12, paragraph before last, classified in class 424, subclass 9.2.

Group VIII. Claims 8, 16, 19-21, drawn to a method for protecting against melanoma in a susceptible subject, who is at risk for development of melanoma, or at risk for recurrence of melanoma, comprising administering an inhibitor of the MAPK pathway, which is PD98059, a small organic molecule, classified in class 424, subclass 9.2.

Group IX. Claims 8, 16, 19-21, drawn to a method for protecting against melanoma in a susceptible subject, who is at risk for development of melanoma, or at risk for recurrence of melanoma, comprising administering an inhibitor of the MAPK pathway, which is U0126, a small organic molecule, classified in class 424, subclass 9.2.

Group X. Claims 8, 16, 19-21, drawn to a method for protecting against melanoma in a susceptible subject, who is at risk for development of melanoma, or at risk for recurrence of melanoma, comprising administering an inhibitor of the MAPK pathway, which is PD184352, a small organic molecule, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1642

The methods of groups I-X are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

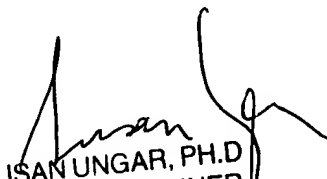
Art Unit: 1642

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. Further, Applicant must indicate which claims are readable upon the elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.



SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

MINH TAM DAVIS

December 2, 2002